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In re Application of: Marcos Intaglietta et al.

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Methods for Increasing Peripheral Blood Circulation

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Assistant Commissioner for Patents Washington, D.C. 20231

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Dated: November 20, 2002

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Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

The Commissioner is hereby authorized to charge any due fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Signed on behalf of:

Dated: November 20, 2002

Maha A. Hamdan

Registration No. 43,655

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Cliff Cannon-Cin

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following patents are referred to in the body of the specification:

- US Patent No. 5,814,601 issued 9/29/98 to Winslow et al.; and
- US Patent No. 5,057,313 issued 10/15/91 to Shih et al..

The following printed publications are referred to in the body of the specification:

- Frangos et al. (1985) Flow Effects on Prostacyclin Production by Cultured Human Endothelial Cells," Science 227:1477-1479;
- de Wit *et al.* (1997) "Elevation of plasma viscosity induces sustained NO-mediated dilation in the hamster cremaster microcirculation in vivo," Phyugers Arch. 434-354-361;

- Malek (1999) "Induction of Nitric Oxide Synthase mRNA by Shear Stress Requires Intracellular Calcium and G-protein Signals and Is Modulated by PI 3 Kinase," Biochem. Biophys. Res. Comm. 254:231-242;
- Dimmeler (1998) "Fluid Shear Stress Stimulates Phosphorylation of Akt in Human Endothelial Cells," Circ. Res. 83:334-341;
- Deb et al. (1999) "Resuscitation with Lactated Ringer's Solution in Rats with Hemorrhagic Shock Induces Immediate Apoptosis," J. Trauma 46:582-589;
- Richardson and Guyton (1959) "Effects of polycythemia and anemia on cardiac output and other circulatory factors," Am. J. Physiol. 197:1167-1170;
- Messmer (1975) "Hemodilution" Surg. Clins N. Am. 55:659-78;
- Mirhashemi *et al.* (1987) "Microcirculatory effects of normovolemic hemodilution in skeletal muscle," Int. J. Microcirc.: Clin.Exp. 6:359-369;
- Johnson (1986) "Autoregulation of Blood Flow," Circ. Res. 59:483-495;
- Lindbom and Arfors (1980) "Influence of Oxygen on Perfused Capillary
 Density and Capillary Red Cell Velocity in Rabbit Skeletal Muscle,"
 Microvasc. Res. 19:197-208;
- Tsai et al. (1998) "Plasma viscosity regulates capillary perfusion during extreme hemodilution in hamster skinfold model," Am. J. Physiol. 275:H2170-H2180;
- Kerger et al. (1996) "Systemic and subcutaneous microvascular PO₂
 dissociation during 4-h hemorrhagic shock in conscious hamsters," Am. J.
 Physiol. 279:H827-H836;
- Schmid Schönbein & Sweifach (1975) "RBC Velocity Profiles in Arterioles and Venules of the Rabbit Omentum," Microvasc Res. 10:153-164;
- Fung et al. (1970) "Elastic Environment of the Capillary Bed," Circ. Res. 19:441-461;
- Intaglietta & dePlomb (1973) "Fluid Exchange in Tunnel and Tube Capillaries,"
 Microvasc. Res. 6:153-168;
- Secomb *et al.* (1987) "Effects of Reduced Perfusion and Hematocrit on Flow Distribution in Capillary Networks," Prog. Appl. Microcirc. 12:205-211;

- Mazzoni et al. (1990) "The Efficacy of Iso- and Hyperosmotic Fluids as Volume Expanders in Fixed-Volume and Uncontrolled Hemorrhage," Ann. Emerg. Med. 19:350-358;
- Tsai *et al.* (1991) "Spatial distribution of red blood cells in individual skeletal muscle capillaries during extreme hemodilution," Int. J. Microcirc.: Clin. Exp. 10:317-334;
- Waschke et al. (1994) "Lack of Dependence of Cerebral Blood Flow on Blood Viscosity After Blood Exchange with a Newtonian O₂ Carrier," J. Cerebral Blood Flow and Metab. 14:871-876;
- Krieter et al. (1995) "Does colloid-induced plasma hyperviscosity in haemodilution jeopardize perfusion and oxygenation of vital organs?" Acta Anaest. Scand. 39:236-244;
- Hermann et al. (1997) "Shear Stress Inhibits H₂O₂-Induced Apoptosis of Human Endothelial Cells by Modulation of the Glutathione Redox Cycle and Nitric Oxide Synthase," Arterioscler. Thromb. Vasc. Biol. 17:3588-3592;
- Dimmeler *et al.* (1999) "Upregulation of Superoxide Dismutase and Nitric Oxide Synthase Mediates the Apoptosis-Suppressive Effects of Shear Stress on Endothelial Cells," Arterioscler. Thromb. Vasc. Biol. 19:656-664;
- Xie et al. (1996) "Role of Endothelium-Derived Nitric Oxide in the Modulation of Canine Myocardial Mitochondrial Respiration In Vitro," Circ. Res. 79:381-387;
- Intaglietta and Zweifach (1973) "Microcirculatory Basis of Fluid Exchange," Advances in Biol. and Med. Phys. 15:111-159;
- Kanzow *et al.* (1982) "Analysis of the hematocrit distribution in the mesenteric microcirculation," Intl. J. Microcirc. Clin. Exp. 1:67-79;
- Klitzman and Johnson (1982) "Capillary network geometry and red cell distribution in hamster cremaster muscle," Am. J. Physiol. 242:H211-H219;
- Lipowsky et al. (1980) "In vivo measurements of hematocrit and apparent viscosity in the microvasculature of cat mesentery," Microvasc. Res. 29:297-319;

- Lipowsky, "Mechanics of Blood Flow in the Microcirculation," Chapter 18, in
 Handbook of Bioengineering, Skalak and Chien, eds., McGraw-Hill Book Co.,
 NY, 1987;
- Sarelius and Duling (1982) "Direct measurement of microvessel hematocrit, red cell flux, velocity and transit time," Am. J. Physiol. 243:H1018-H1026;
- Intaglietta *et al.* (1975) "Capillary Flow Velocity Measurements *In Vivo* and *In Situ* by Television Methods," Microvasc. Res. 10:165-179;
- Messmer *et al.* (1972) "Circulatory Significance of Hemodilution: Rheological Changes and Limitations," Adv. Microcirc. 4:1-77;
- Lipowsky and Firrell (1986) "Microvascular hemodynamics during systemic hemodilution and hemoconcentration," Am. J. Physiol. 250:H908-H922;
- Mirhashemi et al. (1988) "Effects of hemodilution on skin microcirculation,"
 Am. J. Physiol. 254:H411-H416;
- Tigno and Henrich (1986) "Flow Characteristics of the Microcirculation Following Intentional Hemodilution," Acta. Med. Phil. 22:5-12;
- Tigno and Henrich (1986) "Flow Characteristics of the Microcirculation
 Following Intentional Hemodilution, Part II. Hemodynamic response of the pre-capillary arterioles," Acta. Med. Phil. 22:53-58;
- Gustafsson *et al.* (1981) "Effects of increased plasma viscosity and red blood cell aggregation on blood viscosity in vivo," Am. J. Physiol. 241:H513-H518;
- Barbee and Cokelet (1971) "The Fahraeus Effect," Microvasc. Res. 3:6-16;
- Buga et al. (1991) "Shear Stress-Induced Release of Nitric Oxide From Endothelial Cells Grown on Beads," Hypertension 17:187-193;
- Colantuoni et al. (1984) "Quantitation of rhythmic diameter changes in arterial microcirculation," Am. J. Physiol. 246:H508-H517;
- Neumann *et al.* (1980) "A New Highly Potent and Short-acting Analgesic, Carfentanyl (R33799), in Combination with the Hypnotic Agent, Etomidat (R26490), as a Method of Anaesthesia in Guinea Pigs," Res. Exp. Med. (Berl) 177:135-143;

- Lipowsky and Zweifach (1978) "Application of the "Two-Slit" Photometric Technique to the Measurement of Microvascular Volumetric Flow Rates," Microvasc. Res. 15:93-101;
- Filho et al. (1993) "Microvessel PO₂ measurements by phosphorescence decay method," Am. J. Physiol. 34:H1434-H1438;
- Wilson (1993) "Measuring Oxygen Using Oxygen Dependent Quenching of Phosphorescence: A Status Report," Adv. Med. Biol. 333:225-232;
- Vanderkooi et al. (1987) "An Optical Method for Measurement of Dioxygen Concentration Based upon Quenching of Phosphorescense," J. Biol. Chem. 252:5476-5482;
- Chien and Jan (1973) "Red Cell Aggregation by Macromolecules: Roles of Surface Adsorption and Electrostatic Repulsion," J. Supramol. Struct. 12:385-409;
- Gelin (1956) "Studies in Anemia of Injury," Acta Chir. Scand. Suppl. 210:1-130;
- Kroemer *et al.* (1987) "Haemodilution Therapy in Ischaemic Stroke: Plasma Concentrations and Plasma Viscosity During Long-Term Infusion of Dextran 40 or Hydroxyethyl Starch 200/0.5," Euro J. Clin. Pharm. 31:705-710;
- Bruckner et al. (1993) "Organ Blood Supply and Tissue Oxygenation after Limited Normovolemic Hemodilution with 3% versus 6% Dextran-60,"
 Infusionstherapie und Transfusionmedizin 20:130-139;
- Schmidt *et al.* (1993) "Hyperoncotic Ultrahigh Molecular Weight Dextran Solutions Reduce Trypsinogen Activation, Prevent Acinar Necrosis, and Lower Mortality in Rodent Pancreatitis," Am. J. Surg. 165:40-45;
- Chen et al. (1989) "Effects of dextran-induced hyperviscosity on regional blood flow and hemodynamics in dogs," Am. J. Physiol. 256:H898-H905;
- Doss *et al.* (1995) "Mechanism of Systemic Vasodilation During Normovolemic Hemodilution," Anesthesia and Analgesia 81:30-34;
- Intaglietta (1997) "Whitaker Lecture 1996: Microcirculation, Biomedical Engineering, and Artificial Blood," Ann. Biomed. Eng. 25:593-603;

- Smieško and Johnson (1993) "The Arterial Lumen Is Controlled by Flow-Related Shear Stress," NIPS 8:34-38;
- Kuo and Pittman (1988) "Effect of hemodilution on oxygen transport in arteriolar networks of hamster striated muscle," Am. J. Physiol. 254:H331-H339;
- Hudak *et al.* (1989) "Hemodilution cases size-dependent constriction of pial arterioles in the cat," Am. J. Physiol. 257:H912-H917;
- Colantuoni *et al.* (1984) "Effects of anaethesia on the spontaneous activity of the microvasculature," Int. J. Microcirc. Clin. Exp. 3:13-28;
- Funk and Baldinger (1995) "Microcirculatory Perfusion during Volume Therapy," Anethesiology 82:975-982;
- Nolte *et al.* (1997) "Effects of diaspirin-cross-linked hemoglobin (DCLHbTM) on local tissue oxygen tension in striated skin muscle: An efficacy study in the hamster," J. Lab. Clin. Med. 130:328-338;
- Hint (1968) "The pharmacology of dextran and the physiological background for the clinical use of Rheomacrodex and Macrodex," Acta Anaes. Begl. 19:119-138;
- Mirhashemi *et al.* (1987) "Tissue perfusion during normovolemic hemodilution investigated by a hydraulic model of the cardiovascular system," Int. J. Microcirc. Clin. Exp. 6:123-136; and
- Jackson and Duling (1983) "The Oxygen Sensitivity of Hamster Cheek Pouch Arterioles," Circ. Res. 53:515-525.

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- US Patent No. 5,985,825 issued 11/16/99 to Winslow *et al.*, and;
- US Patent No. 6,054,427 issued 4/25/00 to Winslow.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material

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to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

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